

SEP 17 2004

Traditional 510(k) Notification  
RoboCouch Patient Positioning System

Accuray Incorporated

12042146

## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

### **Name, Address, Phone and Fax number of the Applicant**

Accuray Incorporated  
1310 Chesapeake Terrace  
Sunnyvale, California 94089  
Ph: (408) 716-4600  
Fax: (408) 716-4601

### **Contact Person**

Anne Schlagenhaft

### **Date Prepared**

August 5, 2004

### **Device Name**

Trade Name: RoboCouch™ Patient Support System  
Classification Name: Powered radiation therapy patient support assembly

### **Device Description**

The RoboCouch Patient Support System is an electric computer-controlled treatment table for supporting and positioning a patient during radiosurgery, radiotherapy and other medical procedures requiring precise positioning. The RoboCouch is mounted on a robotic arm with 6 degrees of freedom.

### **Intended Use**

The RoboCouch Patient Support System is intended for use in the support and positioning of a patient during radiosurgery and radiotherapy procedures and other medical procedures when precise positioning is required.

### **Substantial Equivalence**

The RoboCouch is substantially equivalent to the CyberKnife® System Patient Support Subsystem and the Elekta Precise Table.

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SEP 17 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Anne Schlagenhaft  
Sr. Regulatory Affairs Associate  
Accuray, Incorporated  
1310 Chesapeake Terrace  
SUNNYVALE CA 94089

Re: K042146  
Trade/Device Name: RoboCouch Patient  
Support Systems  
Regulation Number: 21 CFR 892.5770  
Regulation Name: Powered radiation therapy  
patient support assembly  
Regulatory Class: II  
Product Code: 90 JAI  
Dated: August 5, 2004  
Received: August 9, 2004

Dear Ms. Schlagenhaft:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

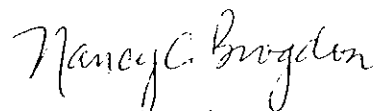
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

*K042146*

Device Name: RoboCouch Patient Support System

Indications For Use:

The RoboCouch Patient Support System is indicated for the support and positioning of a patient during radiosurgery and radiotherapy procedures and other medical procedures when precise positioning is required.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Seymour*  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number *K042146*

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